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Clinical and Radiological Outcomes of Less Invasive Temporary Internal Distraction Followed by Staged Pedicle Screw Instrumentation in Adolescents with Severe Idiopathic Scoliosis at 2-year Minimum Follow-up

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Abstract

Study Design. A single-center, retrospective study with a minimum 2-year follow up.

Objectives. To describe and report the outcomes of minimal invasive temporary internal distraction (MI-TID) in the surgical treatment of adolescents with severe idiopathic scoliosis (SS).

Summary of Background Data. Temporary internal distraction rod is one of the surgical options in severe scoliosis to avoid preoperative halo traction or vertebral column resection. This technique can be applied in a single session or staged and also using magnetically controlled growing rods to facilitate curve correction. Here we report the outcomes of simplistic initial minimal invasive internal distraction surgery followed by definitive segmental pedicle screw instrumentation with posterior column osteotomies.

Methods. Twenty-two consecutive adolescents (19 girls, mean [SD] age 14.8 [2.0] years) with severe idiopathic scoliosis (major curve ≥ 90°), who were treated using the MI-TID followed by staged pedicle screw instrumentation with minimum two-year follow-up. Demographic data, radiographic outcomes, pulmonary function tests (PFTs), perioperative data, Scoliosis Research Society 22 outcome questionnaire, complications, and neuromonitoring (NM) data were collected.

Results. The major curve averaged preoperatively 120° (SD, 31°) and 58° (range 28°–65°) at final follow-up ($p<0.001$). Similarly, thoracic kyphosis (T5-T12) improved from 80° (42°) to 32° (range, 23°– 68°) ($p<0.001$), and spinal height (T1-S1) increased from 332 mm (range, 198-432 mm) to 405 mm (range, 258-495 mm) ($p<0.001$). Five (23%) children had an intraoperative neuromonitoring change without postoperative neurologic deficits and two children developed superior mesenteric artery syndrome treated conservatively. Mean per cent predicted forced vital capacity (FVC) improved from 44.5% (11.3%) to 66.5 (10.8) at final follow-up($p<0.05$). The SRS-22R total score improved significantly from 2.9 (0.61) to 4.1 (0.44) ($p<0.05$).

Conclusion. Staged minimally invasive internal distraction followed by pedicle screw instrumentation is safe and effective in adolescents with severe idiopathic scoliosis improving spinal deformity, pulmonary function, and health-related quality.

Key words: Severe adolescent idiopathic scoliosis; temporary internal distraction; pedicle screw instrumentation; health-related quality of life; pulmonary function.

Level of Evidence: 4

Introduction

Treatment of severe spinal deformities (SSD) is complicated because they may cause compression of the spinal cord and thoracoabdominal structures [1, 2], which may lead to neurological and cardiopulmonary anomalies, thus affecting patient's daily activities, growth, development, and physical appearance [3, 4]. Radical correction of large and stiff curvatures increases the risk of neurological complications. Severe curves of the spine in children and adolescents have historically been treated with HALO traction as a safe presurgical addition, but this method cannot be used consistently due to the long-term treatment facilities required. Other options, such as internal distraction, releases, osteotomies, and apical vertebral resection are often used in combination to achieve optimal results [4-6].

Temporary internal distraction with modern segmental instrumentation was introduced by Buchowski et al. [7, 8] in 2006 and further described with some modifications by Tolo and Skaggs [9]. The original technique included wide whole length posterior spinal exposure, apical osteotomies, and gradual distraction between upper fixation using rib hooks and pedicle screws in the lumbar spine. Segmental pedicle screw instrumentation and final fusion can be performed at the same surgery or staged. Modifications have been reported into this technique, such as the use of conventional growing rods, or the novel magnetically controlled growing rod as an internal distraction device to facilitate increased distraction before final instrumented fusion [10]. Temporary distraction rods provide a significant corrective force directly to the deformed spine to increase the possibility for safer correction manipulations working using the viscoelastic components of the human body. Due to all contraindications and complications of HALO gravity traction or VCR, temporary internal distraction is considered as an alternative to correct severe scoliosis [7-11].

We describe here the technique and outcomes of an initial simplistic minimal invasive surgery temporary distraction using a combination of upper thoracic and lumbar pedicle screws, posterior column osteotomies around the fixation points and tunneled subcutaneous rods with gradual distraction for severe adolescent idiopathic scoliosis. Final fusion was carried using standard segmental pedicle screws and additional apical posterior column osteotomies allowing advanced deformity correction. We hypothesized that staged surgical treatment for SSD with MI-TID and final instrumented fusion with pedicle screws would provide major improvement in the coronal and sagittal deformities as well as pulmonary function, and health-related quality

of life. This could further minimize the risk of complications associated with preoperative halo-gravity traction, and final deformity correction would be easier to achieve.

Materials and Methods

Settings and Patients

This is a retrospective study involving 22 consecutive adolescents with severe idiopathic scoliosis (major curve ≥90°), who were treated with the two stages of surgical procedures (initial mini-invasive internal traction and final deformity correction and fusion with pedicle screws) to determine the safety and efficacy of the treatment in relation to spinal deformity correction, lung function, and health related quality of life (Table 1). All patients were followed with a minimum follow-up of two years. Inclusion criteria included severe idiopathic scoliosis (major curve Cobb >90 degrees) and the two staged surgical procedure with initial mini-invasive temporary internal traction. All patients were treated in the children's hospital by the same experienced orthopaedic spine surgeon between 2016 and 2019. This study was approved by our institutional ethical board.

Outcome parameters

The outcome parameters included clinical characteristics (rib hump), radiographic outcomes, pulmonary function tests (PFTs), perioperative data (operating time, blood loss), complications, and health-related quality of life using SRS-22r questionnaire. All these parameters were collected preoperatively, after the initial distraction surgery, after final fusion, and at two-year follow-up. Complications were reported as implant-related, wound related, deep wound infection requiring irrigation and debridement, and any neurological complications.

Radiographic Parameters

Full-length upright anteroposterior and lateral spinal radiographs were acquired preoperatively, after the first and second stages of surgery, and at the final follow-up. Using these radiographs and the Cobb technique [37] we measured the magnitude of the coronal major curve as well as spinal height (T1-S1) and space available for the lung [7, 9, 11]. T1-S1 length was measured as the distance from the midpoint of the T1 superior end plate to the midpoint of the S1 superior end plate. Using the lateral radiographs and the Cobb technique, we measured the thoracic kyphosis (T5-T12). Preoperative three-dimensional computed tomography was

obtained to plan the surgery and to better delineate the type and etiology of the deformity. Magnetic resonance imaging was performed to exclude of spinal cord pathology.

Pulmonary function tests

Pulmonary function was assessed using a standard ultrasound spirometer in a sitting position preoperatively and at 2-year follow-up. The pulmonary function values included forced vital capacity (FVC) and forced expiratory volume in one second (FEV1), expressed as a percentage of the predicted values (%) [3, 5, 6, 12].

Surgical technique

The surgical technique used was a modification of Buchowski's and Skaggs' methods of internal distraction, which are well-known in the literature [7-11]. Briefly, in the first stage of surgery, patients were placed in prone position after induction of general anesthesia with tracheal intubation. Two short incisions were made, similar to the standard growing rods technique, over the proximal thoracic and lower lumbar spinal regions as presented Figures 1, 2. Pedicle screw placement with posterior column osteotomies were typically performed at levels between T2 and T5 (T6) and between T12 and L4. Two titanium alloy rods 6.0 mm were then measured, cut, and contoured for frontal and sagittal plane alignment. Rods were inserted subcutaneously, connected to pedicle screws, following two-rod synchronic derotation with NM checking as presented Figure 3 and 4. Next, a safe and optimal internal distraction of the spine was performed with NM and blocking of internal temporary rods. This usually applied a 5-6 cm distraction in total, depending on the flexibility of the scoliosis. The wound was then closed in layers. Patients were allowed to sit on the bed 24 hours after the operation, and 48 hours after surgery were allowed to exercise and walk. No postoperative immobilization was used at this stage (Figures 5 and 6).

The second stage was performed 2–6 weeks after the first stage and included Ponte osteotomies on the apex of the curvature, segmental bilateral pedicle screw placement, and final correction with replacement of the Titanium Alloy rods using two contoured 6.0 Cobalt-Chromium rods. First, the left rod was removed and pedicle screws were implanted, while the right sided rod was still in place to prevent loss of correction. Then, we switched a temporary rod to the left side to prevent loss of correction. Next, the right rod was removed and pedicle screws were placed. After posterior exposure and dissection of the paravertebral tissues to allow the rigid spine to become more flexible, deformity was corrected using a combination of rod cantilever and derotation. Decortication was performed on all levels of planned fusion, and

allograft bone was placed in a posterolateral fashion. The wound was then closed in layers over subfascial drains. Patients were allowed to sit on the bed 24 hours after the operation. Drain was removed 48 hours after surgery and patients were allowed to exercise and walk. No postoperative immobilization was used. The postoperative radiographs are shown in Figures 7 and 8. Clinical pictures presented Figure 9, 10 and 11.

Neuromonitoring

All patients underwent SSEP and transcranial MEP monitoring. Pedicle screw stimulation was performed to generate and deliver square wave constant-current pulses to each pedicle screw following insertion. Any track without a palpable medial wall was defined as aberrant and underwent screw re-direction. Attention for signals and MAPs were kept at minimum 80 mmHg or higher during distraction. If there is a genuine NM event, prompt release of distraction should lead to immediate return of MEPs, and significant further distraction is contraindicated [11, 14-16]. Intraoperative NM change from baseline was defined as a 10% increase in latency and/or 50% decrease in SSEP amplitude or MEP absence, unilaterally or bilaterally [11, 13-16].

Statistical analysis

Statistica 10.0 software (StatSoft Inc., Tulsa, Oklahoma, USA) was used for all analyses. Compatibility of distribution in quantitative variables with a normal distribution was examined using the Shapiro-Wilk test and non-parametric tests, as appropriate. The Mann-Whitney U test and the Kruskal-Wallis analysis of variance rank test were used for between-group comparisons, including Cobb angles, coronal curve flexibility, deformity correction, and T1-S1 gain. Results were considered statistically significant when the calculated test probability P was below 0.05.

Results

Nineteen girls and three boys with juvenile or adolescent idiopathic scoliosis were enrolled in this study with a mean (SD) age of 14.8 (1.97) years (Table 1). At the initial distraction surgery, the mean operating time was 183 min (range, 125-262) and the mean total (intraoperative) blood loss was 601 ml (range, 320-1100). At the staged or definitive surgery, the mean operative time was 341 min (range, 226-450) and mean total blood loss 795 ml (range, 450-1100). The mean

interval time between the two surgeries was 3 weeks (range, 2 to 6 weeks). The mean body height increased by 6.2 cm (range, 3.5 – 9.3 cm) at the initial distraction surgery and 2.8 cm (range, 2.8 – 6.5 cm) at the second stage (final fusion).

Radiographic outcomes

The mean preoperative major curve was 120° (range, 90° – 160) and thoracic kyphosis 80° (range, 30° – 120°). The mean preoperative flexibility in the bending films averaged 31% (range, 13 – 47%). After the initial distraction surgery, the mean major curve was corrected to 75° (range, 40° – 86°), and thoracic kyphosis to a mean of 52° (range, 20° – 78°). After the second stage (definitive surgery), the major curve was corrected to 58° (range, 29° – 69°) and thoracic kyphosis (T5-T12) was corrected to 32° (range, 22° – 69°) and these remained stable during the follow-up. The mean preoperative spinal height (T1-S1) improved from 332 mm (range, 198-432) to 405 mm (range, 258 – 495 mm) at final follow-up. The mean preoperative AVT was 8.9 cm (6 – 14 cm) and improved to 2.8 cm (2.5 – 10 cm) at final follow-up.

Pulmonary function

Pulmonary function data are shown in Table 3. The mean (SD) preoperative FVC (percentage predicted) improved from 44.5% (11.3%) to 66.5% (10.8%) at final follow-up ($p<0.05$), and preoperative FEV_1 improved from 42.7% (14.1%) to 67.9% (12.8%) ($p<0.05$). This represents an overall improvement in pulmonary function of approximately 30% from the baseline values.

Health-Related Quality of Life

The mean preoperative SRS-22R [38, 39] total score improved significantly from 2.9 (0.61) to 4.1 (0.44) at final follow-up ($p<0.05$) (Table 4). The SRS-22r questionnaire domains including pain, function, self-image, mental health, and satisfaction showed a clinically and statistically significant improvement from preoperative to final follow-up ($p<0.05$ for all comparisons).

Complications

Five (22%) of the 22 patients (22%) had an intraoperative neuromonitoring change, but none of the patients showed a postoperative neurological deficit. The neuromonitoring changes occurred at the initial distraction surgery (0-5? children) and at the final fusion (0-5? children).

Two patients developed superior mesentery artery syndrome postoperatively, but both resolved conservatively within 12 and 14 days, respectively after the final fusion surgery. There were no deep wound infections or instrumentation related complications during the follow-up.

Discussion

Treatment of SSD is a complicated process. Most spine surgeons choose to correct this kind of complex deformity via various techniques, such as preoperative HALO traction, intraoperative traction, or spinal osteotomies with all-pedicle screws construct, such as VCR [16-20]. However, the deformity is not only an increase in curvature, but also a combination of rigid body changes resulting into decreased flexibility, or even fusion of the spine, which may lead into major difficulties during the surgery for severe scoliosis [21]. Neurological complications of spine deformity surgery in pediatric patients are rare, but potentially devastating [4,11,20-22]. It is certain that three-column osteotomies increase the risk of potential neurological deficits [23,24], and neurological deficits may remain permanently [11].

HALO gravity traction studies indicated that the real effect of HGT on rigid curves may be overestimated. Some authors reported excellent curve correction > 80° with HGT, anterior release, and final posterior correction after aggressive release and longer treatment in hospital for more than 3 weeks [4, 11, 17-19]. Other authors have described correction up to 46% during HALO traction from 3 weeks to 3 months. In our study, the initial minimally invasive distraction surgery occurred without anterior release, but we performed Ponte osteotomies at several levels on the top of the thoracic and lower lumbar spinal regions [25-27]. Our mean final curve correction was 67% (from 140° to 46°). The curve correction rate after internal distraction was better than that achieved with conventional HALO distraction and similar to that obtained from corrective surgery with posterior or anterior release. The final curve correction rate was better than that achieved with conventional HALO distraction but less than that obtained from surgery with VCR. Our study shows that the minimally invasive distraction surgery is a safe technique with good outcomes in coronal and sagittal correction. Comparing the treatment with HALO gravity traction or surgical treatment with VCR, treatment using our MI-TID multi-stage technique is, according to our assessment, a much safer for improving lung function (avoiding costotransversectomy and associated medial rib resection) and correcting spinal deformities. All our patients recovered after surgery without major complications. None of them had respiratory complications or required reintubation or tracheotomy. After surgery, no signs of wound infection or neurological disorder were found in any patient. At the final

follow-up, no effects of pull out implants or back pain syndromes occurred. An additional advantage of temporary internal distraction was a mean increase of 8.6 cm in T1-S1 length, which is a similar outcome as in the study by Skaggs et al [11]. Our study presents a mean Cobb angle correction of 54% using temporary internal distraction. In comparison, VCR leads to 51% to 59% correction [14, 20,23-24,28], but neurological complications after VCR are much more prevalent.

To further decrease the morbidity of the initial distraction surgery, we minimized the initial single long posterior standard incision into two incisions, similar to the standard growing rods technique, on the top of the thoracic and lower lumbar spinal regions and used the same proximal pedicle screws also at the distraction surgery [4,10]. MI-TID has the advantage of avoiding long hospitalization periods, typical in preoperative traction. In a study comparing different surgical techniques for the treatment of idiopathic scoliosis exceeding 90 degrees, anterior release with HALO-femoral traction combined with PSF produced the greatest coronal curve correction, at 53% [17,18]. In the literature some researchers [4] concluded that in severe scoliosis, the main goal should not be maximum curvature correction, but rather to obtain the best, acceptable spine balance. To the best of our knowledge, no reported technique has shown a greater increase in T1-S1 length after correction of severe scoliosis than MI-TID which also notably allowed for a mean 70 % decrease in the apical vertebral translation.

Intraoperative distraction in the form of skull-femoral traction has been associated with neuromonitoring changes. Some studies reported a nearly 50% loss of MEPs in patients undergoing intraoperative skull-femoral traction, compared with 41% in the Skaggs study of internal distraction and 22% in our study [11, 16]. In the past, the incidence of neurological deficits after scoliosis surgery ranged from 0.6% to 17.3% [19,29-33]. NM changes during spinal deformity surgery range from 1.5% to 12.7% [34-36]. In our study 5 out of 22 patients (22%) showed intraoperative NM changes without neurological deficits after waking up. However, in case of NM changes during internal distraction, releasing distraction and optimization of blood pressure led to a return of NM signals to baseline in every instance [11, 22, 27]. The importance of mean arterial pressure (MAP) on the spinal cord perfusion has been well established [36]. MAP would be expected to have the greatest impact on perfusion-based NM changes, as observed in this study showing a lower MAP in bilateral changes than in unilateral changes. Low hemoglobin contributed to a decrease in MAP in a number of cases, and addressing the anemia helped us to elevate MAP. Careful monitoring and management helped to maintain spinal cord perfusion in the perioperative period. Major risk factors for

neurological deficits can include diagnosis of congenital scoliosis, or kyphoscoliosis [11]. However, the intraoperative NM events did not cause any neurological deficits after the operation. In a situation of intraoperative loss of neuromonitoring signals we recommend releasing the distractive forces on the temporary rod with shortening, stop further manipulation, and elevation of MAP to > 100 mmHg, and returning to surgery several days later and continuation distraction. The possibility to stage the surgery is easier with the current method as compared with vertebral column resection resulting into full destabilization of the spine.

Limitations

Our study is limited by the relatively low number of patients and its retrospective nature. However, all of our patients had idiopathic scoliosis with a minimum two year follow-up, all patients were operated by the same experienced orthopaedic spine surgeon with a similar surgical technique. In addition to the standard radiographic and complication data we were able to provide pre and postoperative pulmonary function and health related quality of life data using standardized outcome measurements.

Conclusions

Initial minimally invasive distraction surgery followed by staged segmental pedicle screw instrumentation for severe adolescent idiopathic scoliosis was safe, effective and relatively well tolerated. This technique provided 51% correction of severe AIS, improved percentage predicted forced vital capacity by 49%, and resulted into clinically and statistically very significant improvement in the SRS-22r outcome scores. Twenty-three per cent had an intraoperative neuromonitoring change, but none developed a postoperative neurological deficit. Thus, we conclude that this technique allows for a very significant deformity correction without prolonged traction or an anterior approach. The minimally invasive initial distraction surgery followed for staged segmental pedicle screw instrumentation is a safe and effective alternative treatment for severe and rigid adolescent idiopathic scoliosis.

Legend

Table 1. Baseline clinical, and surgical data for adolescents with a severe idiopathic scoliosis.

Patient	Age, years	Sex	Diagnosis	Prior Surgery	Preop Major Curve	Major Curve Final Follow-up	BL 1 st	BL 2 st	Number of Vertebrae Fused
1	17	M	AIS	No	180	300	350	800	15
2	11	F	AIS	No	165	280	420	650	13
3	15	F	AIS	No	221	320	830	920	14
4	12	F	JIS	No	201	310	510	450	13
5	11	F	JIS	No	262	340	780	890	14
6	13	F	AIS	No	187	450	900	1020	15
7	15	M	AIS	No	164	302	380	730	14
8	17	F	AIS	No	125	321	600	670	14
9	15	F	AIS	No	186	326	450	480	15
10	14	F	AIS	No	190	389	420	600	13
11	14	F	AIS	No	144	226	380	950	12
12	12	F	JIS	No	156	424	320	890	14
13	16	M	AIS	No	245	404	840	1090	15
14	17	F	AIS	No	187	409	400	650	14
15	15	F	AIS	No	145	280	380	780	13
16	13	F	JIS	No	178	302	950	1100	14
17	12	F	JIS	No	133	335	460	500	15
18	11	F	JIS	No	201	352	1100	900	15
19	16	F	AIS	No	225	380	680	1060	14
20	13	F	JIS	No	175	354	750	850	15
21	15	F	AIS	No	182	298	800	620	13
22	14	F	JIS	No	195	414	530	900	14

M – male, F – female, JIS – juvenile idiopathic scoliosis, AIS – adolescent idiopathic scoliosis, N – no, Y – yes, OT – operating time (1st stage, 2nd stage), BL – intraoperative blood loss (1st stage, 2nd stage)

Table 2. Radiological Outcomes.

Parameter by time point	Severe AIS, JIS (N = 22)
Mean major curve, ° (range)	
Preoperatively	120 (90 – 160)
In bending radiographs	81 (59 - 122)
After distraction surgery	75 (40 – 86)
After final fusion	58 (28 – 65)
At final follow-up	59 (29 – 69)
Mean spinal height, T1-S1, mm (range)	
Preoperatively	332 (198 – 432)
After distraction surgery	392 (234 - 472)
After final fusion	400 (265 – 498)
At final follow-up	405 (258 – 495)
Mean apical vertebral translation, mm (range)	
Preoperatively	89 (60 – 140)
After distraction surgery	50 (35 - 100)
After final fusion	29 (27 – 91)
At final follow-up	28 (25 – 100)
Mean thoracic kyphosis, T5-T12, ° (range)	
Preoperatively	80 (30 – 120)
After initial surgery	52 (20 – 78)
After final fusion	32 (23 – 68)
At final follow-up	33 (22 – 69)

AIS, Adolescent idiopathic scoliosis; JIS, juvenile idiopathic scoliosis

Table 3. Pulmonary function data.

Parameter by time point	Severe AIS, JIS (N = 22)
Mean Forced vital capacity, per cent of predicted (range)	(SD)
Preoperatively	44.5 (11.3)
After distraction surgery	53.7 (12.9)
After final fusion	67.2 (7.9)
At final follow-up	66.5 (10.8)
Mean forced expiratory volume in one second, per cent of predicted (range)	
Preoperatively	42.7 (14.1)
After initial surgery	53.2 (9.5)
After final fusion	69.8 (9.2)
At final follow-up	67.9 (12.8)

Table 4. Scores of the SRS-22R in the surgical study groups. Values are mean (SD).

SRS-22R	Preoperative (N=22)	Final follow-up (N=22)	P values*
Function	2.76 (0.71)	4.22 (0.57)	< 0.05
Pain	3.19 (0.78)	3.83 (0.66)	< 0.05
Self-image	2.82 (0.78)	3.98 (0.76)	< 0.05
Menthal health	2.72 (0.68)	3.85 (0.69)	< 0.05
Satisfaction	2.79 (0.75)	4.01 (0.62)	< 0.05
Total score	2.88 (0.61)	4.11 (0.44)	< 0.05

*Statistical comparisons were performed using the Kruskal-Wallis test.

Figure 1. Standard approach to placement growing rods.

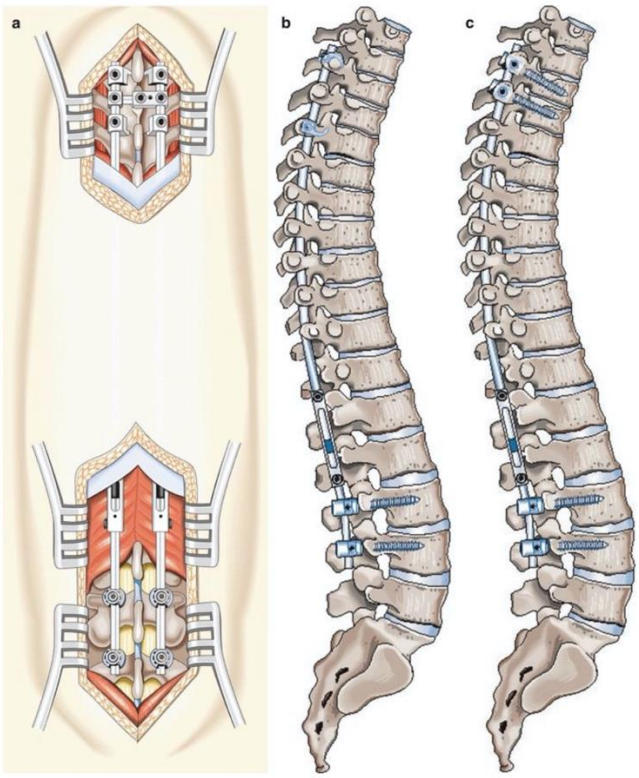
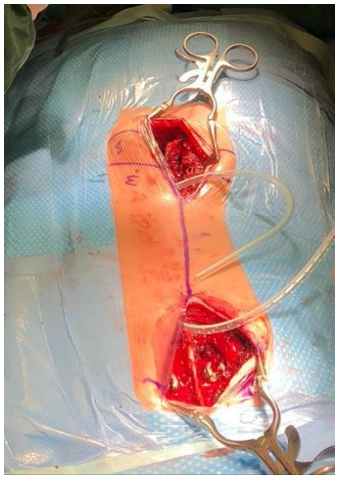


Figure 2. Our approach for minimal invasive temporary internal distraction rods (two incisions, two drains for minimal invasive rods placement)



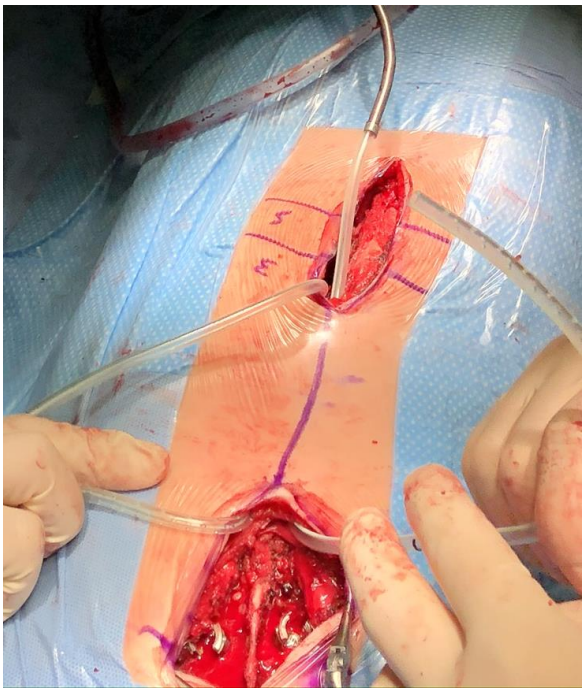


Figure 3. 15-y.o. girl before staged surgical treatment, standing X-Rays AP/L, bending films

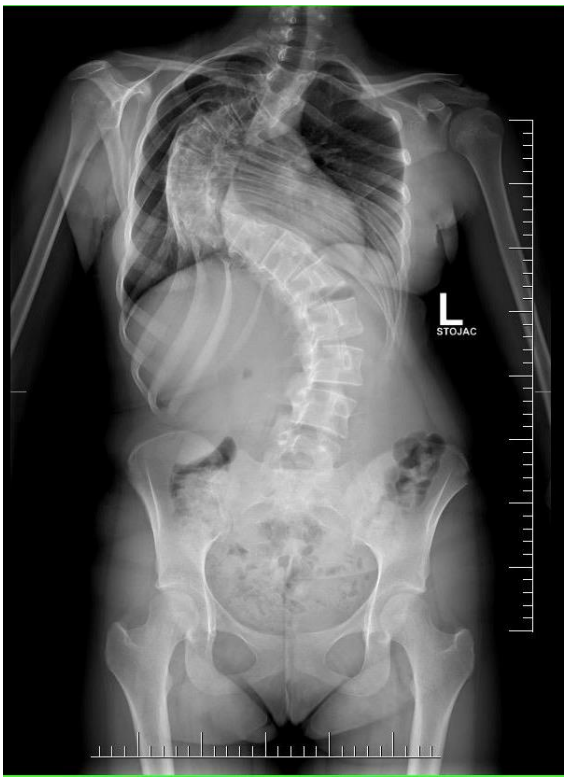



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Figure 4. X-rays after I stage

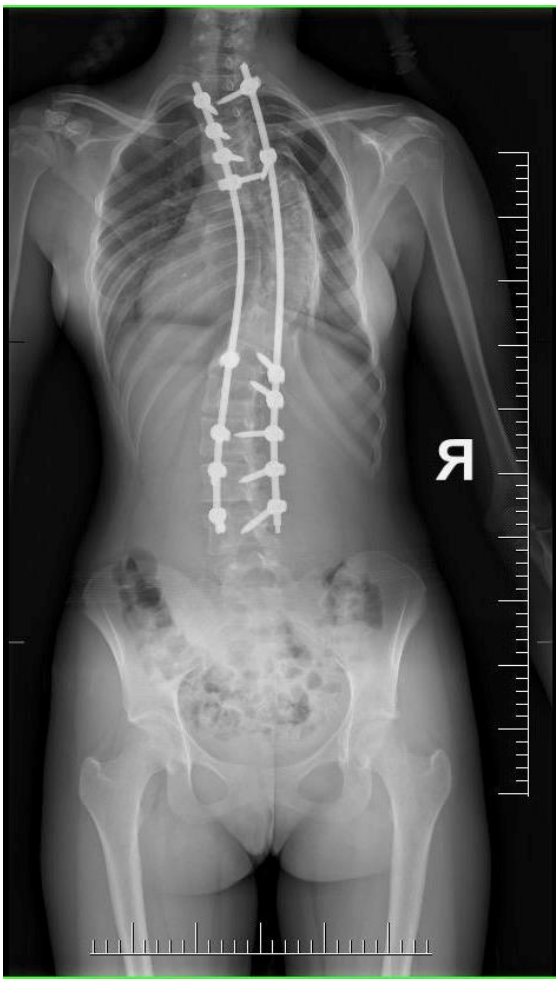


Figure 5. X-rays after final stage

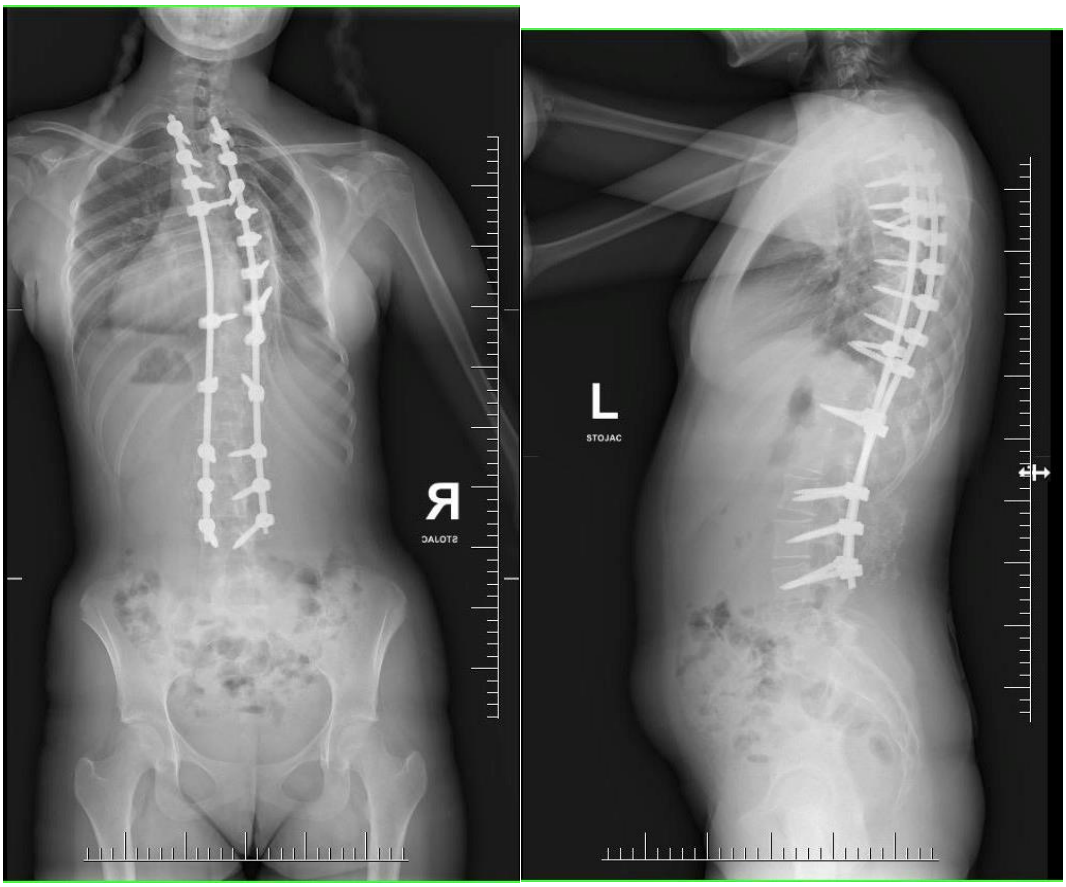
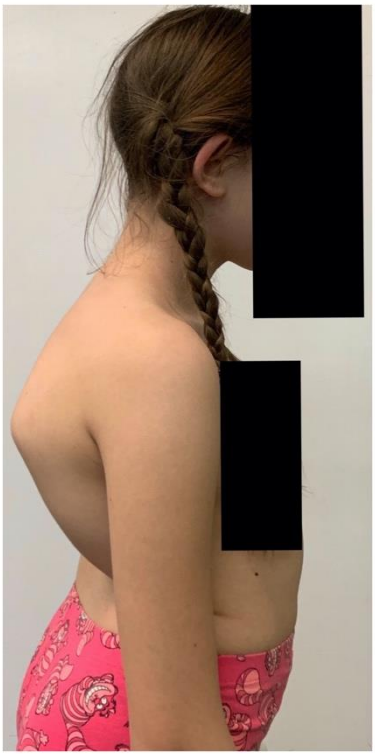


Figure 6. Clinical photo before staged surgery and at FFU



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